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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,131	08/23/2001	Jonathan Zmuda	LIO 2 0081	1717

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Richard J. Minnich
FAY, SHARPE, FAGAN, MINNICH & MCKEE, LLP
Seventh Floor
1100 Superior Ave.
Cleveland, OH 44114-2518

EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,131	ZMUDA ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Claims 1, 2, 6-8, 10-12, 14 and 15 were amended in Paper No. 9. Claims 1-15 are pending and under examination.

The revised abstract is acknowledged. Because the material that was deleted from the original abstract does not appear to exist elsewhere in the specification in the same form, Applicant may wish to amend the specification to contain the paragraph that was deleted from the abstract in Paper No. 9.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-10 remain confusing because the recited limitations of using a non-antibody molecule to "tag all classes of antibodies" (claim 8), wherein the molecule is Protein LA (claim 9), or of using anti-human IgG+IgM+IgA antibody cocktail (claim 10) would appear to contradict the purpose of claim 7, which recites "screening for the presence of anti-HCV molecules of the IgA class." Practicing claims 8-10 as recited would result in labeling all antibody classes, not just IgA as recited in claim 7, making it entirely unclear what method Applicant intends to claim.

Applicant has explained that all antibody classes are labeled, that immobilized HCV antigens selectively bind to the labeled anti-HCV antibodies, and that the bound and labeled anti-HCV molecules are what is detected and measured to signify the presence of HCV.

Applicant's explanation has been considered but the claims remain indefinite. Claim 7 is drawn to a method for screening oral fluid samples for the presence of anti-HCV molecules of the IgA class (the preamble of the claim), and detecting the presence of anti-HCV molecules of the IgA class (step (e)), not for screening for and detecting the presence of anti-HCV molecules of all classes, as would be the result of practicing the limitations recited in claims 8-10, nor for the presence of HCV, as Applicant's remarks would indicate. The limitations of claims 8-10, as well as Applicant's remarks, are inconsistent with the stated purpose of claim 7.

Claim 11 remains indefinite because it recites "A method for determining the genotype of HCV virus in a patient" but still does not recite sufficient steps for accomplishing genotype determination.

Since it is apparent that recitation of sufficient steps for accomplishing genotype determination depends on the presence of immobilized genotype-specific HCV peptide antigens at step (c), claim 11 remains indefinite and incomplete.

Applicant is cautioned against the introduction of new matter in amending the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 6, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre et al. in view of US Patent 5,942,407 to Liotta et al. and of US Patent 5,695,930 to Weinstein et al., all of record, for reasons of record.

Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre et al. in view of Liotta et al. and Weinstein et al. as applied to claim 1 above, and further in view of US Patent No. 5,965,390 to Bjorck et al., of record, for reasons of record.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taliani et al., of record, in view of US Patent 5,942,407 to Liotta et al., for reasons of record.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,054,264 to Chien et al., of record, in view of McIntyre et al. and of US Patent No. 5,942,407 to Liotta et al., both cited above, for reasons of record.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,054,264 to Chien et al., McIntyre et al. and Liotta et al. as applied to claim 11, above, and further in view of US Patent No. 5,965,390 to Bjorck et al., for reasons of record.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al., McIntyre et al, and Liotta et al. as applied to claim 11, above, and further in view of Weinstein et al., for reasons of record.

Applicant has pointed out that according to the instant invention, all antibodies are labeled, and by that using the flow-through affinity matrix which has immobilized HCV peptide antigens, any labeled anti-HCV molecules, if present in the sample, are selectively captured and detected. Applicant has quoted that Examiner as stating that "no motivation exists for labeling all antibodies in a sample." Applicant has argued that "it is through the use of a labeled detection molecule that recognizes all classes of immunogens (*sic*; immunoglobulins?) that an enhanced ability to detect anti-HCV in oral fluid is achieved using the flow through affinity matrix"; that the fact that IgG may also be present is irrelevant to the claimed invention; that detection of IgA is what is critical, and is difficult to achieve using prior art methods; and that there is no motivation in the art to label all antibodies in an oral sample and to selectively capture and detect only labeled anti-HCV molecules in a flow through affinity matrix.

These arguments have been considered but not found persuasive. First, the requirement for labeling of "all" antibodies is not a limitation that clearly appears in the claims. Further, Examiner's complete statement regarding lack of motivation in the previous Office action was made in the context of discussing the absence of prior art that teaches the confusing subject matter of claims 8-10, and it was stated that "one of skill in the art would not be motivated to label all classes of antibodies for detection in order to detect IgA." It is appreciated that claims 2, 4, 6, 8-10, 13 and 14 require

labeling of all classes of antibodies that are present. Claims 1, 3, 5, 7, 12 and 15 do not recite that limitation. Applicant's statement that "IgG may also be present is irrelevant to the claimed invention" is not understood, since it would seem that any improvement in sensitivity to be gained from detecting all classes of antibodies in oral fluid would occur as a result of being able to detect the total signal from any and all of the anti-HCV IgG, IgA, and IgM present in the sample. Detecting all classes of anti-viral antibodies in an oral fluid sample is taught by Weinstein et al., which was cited as demonstrating that the use of goat anti-human IgG+IgM+IgA antibody cocktail results in a particularly sensitive and rapid immunoassay for detecting anti-viral antibodies in saliva.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is

703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
August 4, 2003